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August 30, 2000

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Orchex combines rich nutrients from plant and animal sources to promote nervous system balance.
- (2) The soybean component found in Orchex is a natural source of lecithin – a recognized phospholipid and “brain” food. The B-complex vitamins are heavily involved in nervous system health. The essential fatty acids and B-complex vitamins found in grain germ promote a sustaining effect on the nerves. Manganese assists in fatty acid synthesis, enhancing nutritional value. The blend of these different ingredients work together as a calmative to help establish and maintain balanced function of the nervous system.
- (3) The active components, associated nutritional factors, and adaptogenic effects of glandular tissue, plus Cytosol™ extract – rich with whole materials produced by a specific gland, encourage healthy functioning of the target tissues. The essential fatty acids and B-complex vitamins found in wheat germ assist in the timely transmission of nerve impulses and are needed for the appropriate development and functioning of the brain. Soybeans provide phospholipids that are actively involved with intricate chemical processes in both the central and peripheral nervous systems. This powerful blend helps the pieces of the nervous system to function in harmony.
- (4) Promotes tranquility.
- (5) The multiple nutrients found in Orchex work together to encourage mental focus, enhance the ability to relax, and allow greater adaptability to life's constant changes.
- (6) Contains unique glandular materials of Cytosol™ extract that support the corresponding organs in humans.

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Whole Food Supplements

These statements are made for a dietary supplement containing a proprietary blend of bovine liver, bovine orchic Cytosol™ extract, calcium lactate, manganese lactate, porcine stomach, bovine spleen, ovine spleen, soy (bean), defatted wheat (germ), magnesium citrate, bovine brain, and ascorbic acid. Other ingredients include gelatin, niacinamide, water, calcium stearate, potassium para-aminobenzoate, pyridoxine hydrochloride, and natural colors. The name of the product is Orchex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

